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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/628,999 | 07/28/2003 | Rudolf Edgar Falk | 63414CON2(49917) | 7333 |

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| EXAMINER | |
|---|---|
| MAIER, LEIGH C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

DATE MAILED: 05/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/628,999 | FALK ET AL. | |
| | Examiner | Art Unit | |
| | Leigh C. Maier | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *284-286 and 288* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *284-286 and 288* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Status of the Claims*

Claims 275-283 and 289-296 have been canceled. Claims 284-286 and 288 are pending. Any rejection or objection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 USC § 112*

Claims 284-286 and 288 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, as set forth in the previous Office action. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Applicant's arguments filed March 6, 2006 have been fully considered but they are not persuasive. It appears to be Applicant's position that the examples presented in the specification provide the written description of the generic compositions. Applicant cites the example of patient 1 "who received DMSO a chemotherapeutic agent [component 1(i)], hyaluronic acid [component 1(ii)] followed by hyaluronic acid [component 2(i)] and indomethacin[component 29ii)]." First of all, it is not clear how in this context DMSO could be extrapolated to describe the genus "chemotherapeutic agents," when the specification describes DMSO as a "penetration enhancer" or a treatment for edema.

The examiner agrees that the specification present "dozens of examples," 40 examples, in fact, and Applicant provides a table indicating how 28 of these 40 examples allegedly apply to the claims. It is noted that Applicant admits that eight of those 28 are *not applicable to the claims*. It is the examiner's position that not only do the examples not provide adequate written description for the claimed genus, several of the examples that Applicant deems descriptive, are not even consistent with the limitations of the claims. For example, at a minimum the claims require two dosage amounts of [some agent] in combination with HA wherein the two dosage amounts are not the same. Take Case X, for example. This patient is treated with "low dose chemotherapy and the carrier/penetrating molecule, hyaluronic acid." There is no indication of two different dosage amounts. The same is true for Case XVII. The examiner maintains that there is no clear guidance in the specification that leads one to the claimed generic compositions or any indication that Applicant had possession of said generic compositions.

With respect to claim 288, Applicant states in the table that the treatments for patient 9 and patient 17 are applicable, possibly because these are the only examples that use novantrone. However, it is not clear how these examples describe a composition comprising diclofenac.

Claims 284-286 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the previous Office action.

Applicant's arguments filed March 6, 2006 have been fully considered but they are not persuasive. Applicant presents definitions of (1) "chemotherapeutic drug," (2) "anti-cancer drug" and (3) "drug suitable to treat cancer." Applicant does not present any evidence that one of

ordinary skill would be apprised of the metes and bounds of these categories, particularly "drug suitable to treat cancer." Applicant defines such drugs as "molecules that may not be cytotoxic but could be used in combination with cytotoxic agents to produce slowing, regression or eradication of cancer." This definition would appear to include any pharmaceutically acceptable excipient for the administration of "anti-cancer drugs" or "chemotherapeutic drugs" and is much more broad than one of ordinary skill would surmise without having this particular definition. This definition is not in the specification. Further regarding "chemotherapeutic drugs," when such drugs are described in the specification, they are drawn only to those having well-known utility in treating cancer.

***Claim Rejections - 35 USC § 103***

Claims 284-286 are again rejected under 35 U.S.C. 103(a) as being unpatentable over DELLA VALLE et al (US 5,166,331) in view of FRANCHI et al (Rec. Prog. Med., 1989 – abstract) and WOOD (US 4,912,136), as set forth in the previous Office action.

Applicant's arguments filed March 6, 2006 have been fully considered but they are not persuasive.

It appears to be Applicant's position that Della Valle discloses only that which is set forth in the claims of the Della Valle patent and does not address that which was cited in the action other than repeating it. Applicant further argues in a piecemeal manner that neither Franchi nor Wood mention HA or the treatment of cancer. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding Applicant's intended use, the treatment of cancer, intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, this intended is not recited in the claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
May 19, 2006